K042381

DEC 2 8 2004

510(k) Summary

General Information

Date Compiled	August 30, 2004
Classification	Class II
Trade Name	Coronary Sinus Visualization System
Submitter	Acumen Medical, Inc. 1400 Terra Bella Blvd. Suite A Mountain View, CA 94043 Tel: 650 352 5700 Fax: 650 352 5700
Contact	Marybeth Gamber Director, Regulatory Affairs

Intended Use

The Acumen Coronary Sinus Visualization System is intended to aid in the visualization of the coronary sinus, provide temporary occlusion during a venogram, and to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

Predicate Devices

Attain™ Prevail® Left Heart Delivery System K032622
Manufactured by Medtronic Inc.

Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter K973298
Manufactured by Cardima Inc.

ImagCath™ Coronary Angioscope K952638
Manufactured by Baxter Healthcare Corp.

CCD Solid State Video Camera K855529
Manufactured by Medical Dynamics, Inc.

Battery Powered Endoscopic Light Source K960081
Manufactured by Mitsubishi Cable America Inc.

Device Description

The Acumen Coronary Sinus Visualization System (CSVS) is a single-use percutaneous catheter intended to aid in the visualization of the coronary sinus, provide temporary occlusion during a venogram, and to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

The CSVS is a steerable angioscopic catheter with a silicone balloon on the distal end. The balloon is intended to displace blood flow to aid in visualization and to provide temporary occlusion during a venogram. The CSVS includes an integrated light source and a camera providing NTSC video output.

Materials

All materials used in the manufacture of the CSVS are suitable for this use and have been used in numerous previously cleared products.

Testing

In-vitro and *in-vivo* testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

Acumen Medical believes the CSVS is substantially equivalent to the predicate products. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2004

Acumen Medical, Inc.
c/o Ms. Marybeth Gamber
1400 Terra Bella Blvd.
Mountain View, CA 94043-1884

Re: K042381
Trade Name: Coronary Sinus Visualization System, model CSVS 5508
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: II (two)
Product Code: DQY
Dated: August 30th, 2004
Received: September 1st, 2004

Dear Ms. Gamber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4591. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

Indications for Use

510(k) Number (if known):	This application
Device Name:	Acumen Coronary Sinus Visualization System
Indications for Use:	The Acumen Coronary Sinus Visualization System is intended to aid in the visualization of the coronary sinus, provide temporary occlusion during a venogram, and to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042381